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10/566,559	09/18/2006	Sheryl Smith	1181-19 PCT US	6149

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EXAMINER	
BALLARD, KIMBERLY	
ART UNIT	PAPER NUMBER
1649	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,559	SMITH ET AL.	
	Examiner	Art Unit	
	Kimberly Ballard	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *1-6,11-20 and 22-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-10 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/06/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II, claims 7-10 and 21, drawn to a method of screening for a drug which decreases expression of the $\alpha_4\beta_2\delta$ subunit of $GABA_A$, and species election of the method of screening with specific steps as recited in claim 8, in the reply filed on June 23, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-6, 11-20 and 22-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 23, 2009.

3. Accordingly, claims **7-10** and **21** are under examination in the current office action.

Information Disclosure Statement

4. The information disclosure statement (IDS) filed December 6, 2006 has been considered and is of record (see attached form 1449).

Claim Rejections - 35 USC § 112, first paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 9, 10 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 9 recites a drug that decreases expression of the $\alpha_4\beta_2\delta$ subunit of $GABA_A$ and which is identified by a screening method of claim 7 or 8. Claims 10 and 21 are directed to methods of treatment, comprising administering a therapeutically effective amount of a drug of claim 9, as identified by the screening method of claim 7 or 8. Thus, the claims are drawn to a genus of potential drugs and methods of using a genus of to-be-identified drugs, wherein the drugs are defined by what they do, not by what they are. These claims are considered "reach through" claims in that the specification hypothesizes the drug's existence and posits a screening assay which could be performed to identify the drug(s) from a library of candidate compounds.

In the instant case, applicant has not described the structures of a reasonable number of members of the genus now claimed, but rather has presented the public with an idea of how to perform an assay that might identify some agents that fall within the scope of the claim. The specification fails to set forth the structure of the agents which are to be used for administration in the claimed methods. Because no structure is listed in the claims, the skilled artisan could not determine what structures are encompassed by the claims. Rather than describing to the public the actual invention, the claims and

specification describe to the public a plan for obtaining it. Of course what is actually identified in the screening assay depends upon what compounds are screened. If a library of antibodies is screened, the assay might identify some antibodies. Similarly, if a library of small organic molecules is screened, the assay might identify some small organic molecules. However, knowing how to do the steps of the assay does not describe the invention now claimed, which is a pharmaceutical drug and a method of administering the drug for treatment.

A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v. Eli Lilly & Co.*, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention". Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

The instant claims are often referred to as "reach-through" claims, where an applicant attempts to obtain patent protection on an invention not yet discovered. The Court of Appeals for the Federal Circuit addressed claims of this sort in great detail in *University of Rochester v. G.D. Searle and Co.* (69 USPQ 2nd 1886, CAFC 2004). In *Rochester*, the Federal Circuit upheld the district court's ruling that patent claims which recited administration of compounds not disclosed, but rather to be identified in a screening assay, were invalid on their face. The instant claims are drawn to a drug and methods of administering the same for therapeutic use, and thus are directly analogous to the situation in *Rochester*. Since the specification does not disclose to the public the structures claimed, it does not meet the written description requirement of 35 U.S.C. 112, first paragraph.

7. Claims 9, 10 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative

skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988).

The claims are broadly drawn to a drug that decreases expression of the $\alpha_4\beta_2\delta$ subunit of $GABA_A$, and administration of the drug for the treatment of subjects at risk for alcoholisim or premenstrual anxiety, wherein the drug is identified by the screening assay of claims 7 or 8. Thus, the claims comprise the use of a genus of yet-to-be-identified agents that are described only functionally and not structurally.

In the instant case, the nature of the invention is complex. The claims are broad in that they are drawn to administration of a genus of potential drugs which decrease the expression of the $\alpha_4\beta_2\delta$ subunit of $GABA_A$. The specification fails to set forth working examples of drugs that decrease expression of the $\alpha_4\beta_2\delta$ subunit of $GABA_A$, nor are there examples of such agents that demonstrate therapeutic efficacy. The nature of the invention is the demonstration that withdrawal from progesterone following chronic administration (subcutaneous implanted pellet) in female rats (a simulated model of premenstrual syndrome) leads to an increase in α_4 and δ subunit expression in hippocampal neurons, and an increase in neuronal response to the $GABA_A$ partial agonist, THIP, as well as low concentrations of alcohol. These animals also were noted to have a decreased acoustic startle response (a measure of behavioral excitability) following lose dose administration of alcohol. Applicants also demonstrate that withdrawal from chronic alcohol results in increased α_4 subunit expression and decreased δ subunit expression in hippocampal neurons of rats, as well as decreased responsivity of these neurons to subsequent ethanol exposure.

While the skill level in the art is high, the level of predictability is low. While subunit colocalization studes have provided some data regarding the relative abundance of different subunit combinations as well as their regional and cellular distribution, the art recognizes that there is no definitive information yet available on the subunit composition of native $GABA_A$ receptors in the brain (see Feldman et al. Principles of Neuropsychopharmacology, 1997, paragraph spanning pp. 431-432). The art also recognizes that there are regional differences in the mechanisms of ethanol potentiation of $GABA_A$ receptor-mediated responses, as well as the sensitivity to such potentiation (see Feldman, p. 431, 1st column). However, the expression of recombinant $GABA_A$ receptor subunits and various combinations of these subunits in heterologous systems for pharmacologic study –particularly with respect to ethanol sensitivity – is noted to often yield unpredictable results, particularly when coupled with the data from behavioral experiments involving knockout mice (reviewed at pp. 156-158 of Borghese et al. *Alcohol*, 2007 May; 41(3):155-162). Hence, the art to which the present invention relates is complex and highly unpredictable.

Applicant's invention is predicated on the finding that progesterone withdrawal (i.e., premenstrual syndrome model) increases $GABA_A$ receptor δ subunit expression and ethanol withdrawl decreases it as well as decreases the response to alcohol. Applicant extrapolates this result into a method for screening for agents which decease $\alpha_4\beta_2\delta$ subunit expression, and further extrapolates that these drugs can be used therapeutically for the treatment of subjects at risk for PMS and/or alcoholism. Accordingly, it would appear that Applicant provides a single finding (modulation of δ

subunit expression) and then presents an invitation to experiment to assay for agents capable of achieving this effect to be used therapeutically.

In order to practice the claimed invention, therefore, the skilled artisan would have to discover, on his or her own, drugs which are capable of decreasing $\alpha_4\beta_2\delta$ subunit expression. Additionally, the artisan would also have to determine the unique patient population to which the drug is to be adminstered: subjects at risk for alcoholism in the case of claim 10 and subjects at risk for premenstrual anxiety in the case of claim 21, for which each determination requires its own unique diagnostic screening method. The drugs are required starting materials for the claimed methods, but the specification does not teach the artisan how to make and/or use these materials, or from which sources they should be obtained. While it is possible that the artisan could perform the claimed screening assay to identify such drugs, this is not sufficient to indicate how to actually make (or obtain) the starting materials required for the claimed product and methods. As noted above, the genus of potential drugs determined by the screening assay is very broad, and the structures for these diverse agents is not sufficiently described. The specification does not disclose how to make the full genus of agents that might be found in the screening assay, as what is identified in the screening assay is entirely dependent upon what chemical compounds are screened. Thus, the artisan would have to resort to undue experimentation to practice the claimed method, as the artisan would have to invent or discover the appropriate agents on his or her own. Given the lack of guidance as to what structures are encompassed by these drugs and

their use, the large degree of experimentation that would have to be undertaken to make and/or use the agents required in the claimed invention would be undue.

A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genetec, Inc. v. Novo Nordisk*, 42 USPQ 2d 100, (CAFC 1997), the court held that: "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure." The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement". The instant specification is therefore not enabling because one cannot follow the guidance presented therein and practice the claimed method without first making a substantial inventive contribution.

Due to the large degree of experimentation that would be required to identify drugs capable of decreasing decreasing $\alpha_4\beta_2\delta$ subunit expression, the large breadth of the claims, the lack of working examples and guidance in the specification directed to the same, the complex nature of the invention and the unpredictability of the related art,

undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 10 and 21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-5 of copending Application No. 12/075,159 (hereinafter the '159 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '159 application contains claims directed to a method of treating anxiety or irritability comprising administering a regulator which decreases expression of the alpha 4 subunit of GABA which would render obvious the instantly claimed therapeutic methods which

comprise administration of a drug that decreases expression of the alpha4beta2delta subunit of GABA. The regulator gabadoxbol (THIP) recited in the '159 application is a species that renders obvious the genus of drugs recited in the presently claimed method. Additionally, the '159 application recites treatment of PMS (as in present claim 21) and treatment of anxiety, irritability, and chronic stress, which are symptoms commonly associated with alcoholism (as in present claim 10).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Gault et al. (*J Neurochem*. 1998; 70:1907-1915).

Gault et al. teach a method of measuring the expression of the $GABA_A$ receptor δ subunit in cultured rat cerebellar granule neurons. In particular, Gault discloses isolating and culturing cerebellar granule neurons from Sprague-Dawley rats (see "Cell culture" on p. 1908), which addresses step (a). Gault also teaches applying various drugs to the cultured neurons, such as the NMDA receptor antagonist MK801 and the CAM kinase inhibitor KN-62 (see p. 1911). Addition of these agents each caused a

decrease in δ subunit mRNA expression in the cultured neurons compared to neurons not treated with the agents (see, in particular, Fig. 5 for MK801-induced decrease and Fig. 7 for KN-62-induced decrease). Accordingly, Gault teaches the recited steps of (b) through (e), and thus MK801 and KN-62 are drugs identifed by the method. *Integra Life Sciences I Ltd. v. Merck KGaA,* 50 USPQ2d 1846 (DC S. Calif, 1999) teaches that a reference teaching a process may anticipate claims drawn to a method comprising the same process steps, despite the recitation of a different intended use in the preamble or the later discovery of a particular property of one of the starting materials or end products. Thus, the teachings of Gault et al. are anticipatory for the claimed invention.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/10637 by LeBourdelles et al. (published April 11, 1996) in view of Smith et al. (Abstract from the 11th Congress of the International Society for Biomedical Research on Alcoholism. *Alcoholism Clinical Exp Res*. 2002 May; 26(5 Suppl):16A, Abstract #65).

LeBourdelles et al. disclose methods of stably co-transfecting eukaryotic cell lines to express a $GABA_A$ receptor, and methods of using these cell lines in screening and design of drugs which action upon the $GABA_A$ receptor (see Abstract and p. 9). LeBourdelles teaches that the eukaryotic host cell is to be transfected with at least three expression vectors, each harboring cDNAs encoding for an α_4, β, or δ $GABA_A$ receptor subunit (see p. 6). LeBourdelles notes that it is necessary to incorporate the α_4 subunit, at least one β subunit, and the δ subunit into the cell line in order to produce the required receptor, although the choice of the receptor subunit combination can vary according to the type of activity or selectivity which is being screened or (see paragraphs spanning pp. 7-8). Therefore, LeBourdelles discloses, it is preferable to

build up a library of cell lines, each with different combinations of subunits. For example, in addition to the already noted GABAA receptor subunit combination, combinations can include (α_4 or α_6), (β_2 or β_3) and (δ or γ_2) (see p. 8, lines 3-8). LeBourdelles teaches that these stably-transfected eukaryotic cell lines can then be used in screening for and designing medicaments which act upon the $GABA_A$ receptor.

Thus, LeBourdelles teaches a method of screening for a drug which acts upon the GABAA receptor comprising: (a) expressing $\alpha_4\beta_2\delta$ $GABA_A$ receptors in eukaryotic cells; (b) applying a drug to the eukaryotic cells of (a); and determining whether the drug modulates the $\alpha_4\beta_2\delta$ $GABA_A$ receptor in some manner to thereby identify a drug which acts upon the $\alpha_4\beta_2\delta$ subunit of the $GABA_A$ receptor. The difference between the LeBourdelles document and the instant invention is that the prior art reference does not teach measuring the expression level of the δ subunit of $GABA_A$ receptor for drug screening.

Smith et al. teach modulation of $\alpha_4\beta_2\delta$ $GABA_A$ receptors following withdrawal from chronically administered progesterone in female rats. For pharmacological studies, $\alpha_4\beta_2\delta$ $GABA_A$ receptor responses were assessed by measuring the level of α_4 and δ subunit expression and also by voltage-clamp recordings. Further, Smith correlated the *in vitro* data to *in vivo* behavioral responses in the animals, noting that progesterone withdrawal leads to greater sensitivity to low doses of ethanol, presumably through the enhanced expression of $\alpha_4\beta_2\delta$ GABAA receptors observed following withdrawal.

Therefore, it would have been obvious to one of skill in the art at the time the invention was filed to utilize the types of measurements taught by Smith et al., such as

measuring the expression of α_4 and δ subunits, in the screening method taught by LeBourdelles so as to arrive at the claimed invention. This is because the skilled artisan has good reason to pursue the known options within his or her technical grasp to obtain predictable results. Such would amount to the simple combining of prior art elements according to known methods (i.e., pharmacologic assessment of $GABA_A$ receptor modulation) to obtain predictable results. As noted by the United States Supreme Court, if a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *KSR,* 127 S. Ct. at 1740. "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show it was obvious under 35 U.S.C. 103." *KSR Int'l Co. v. Teleflex Inc.,* 127 S.Ct. 1727, 1742, 82USPQ2d 1385, 1396 (2007).

Conclusion

14. No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Ballard whose telephone number is 571-272-2150. The examiner can normally be reached on Monday-Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kimberly Ballard
Art Unit 1649

/Daniel E. Kolker/
Primary Examiner, Art Unit 1649
August 15, 2009